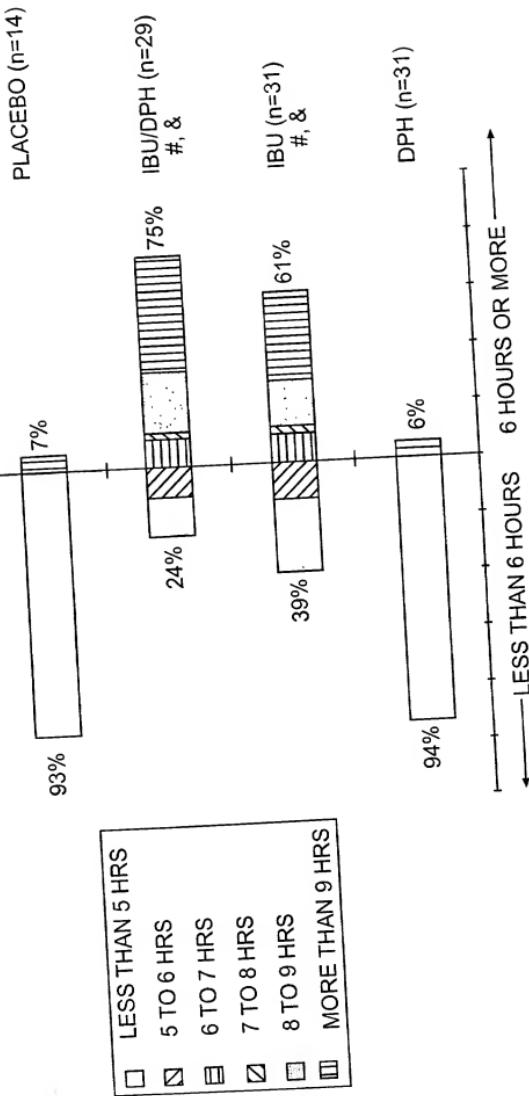


SLEEP LATENCY AND DURATION OF SLEEP
STUDY A



#: SIGNIFICANTLY BETTER THAN PLACEBO;
&: SIGNIFICANTLY BETTER THAN DPH.
NOTE: ALL TESTING WERE DONE AT 0.075 LEVEL OF SIGNIFICANCE

FIG. 1

NURSE OBSERVED SLEEP LATENCY
STUDY A

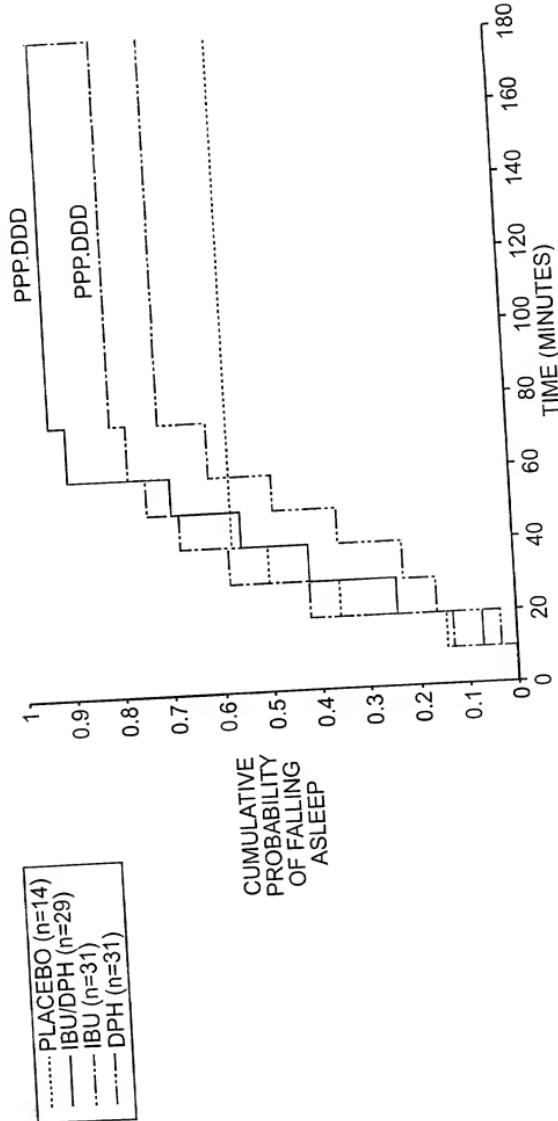


FIG. 2

MEAN SPRID3 SCORES
STUDY A

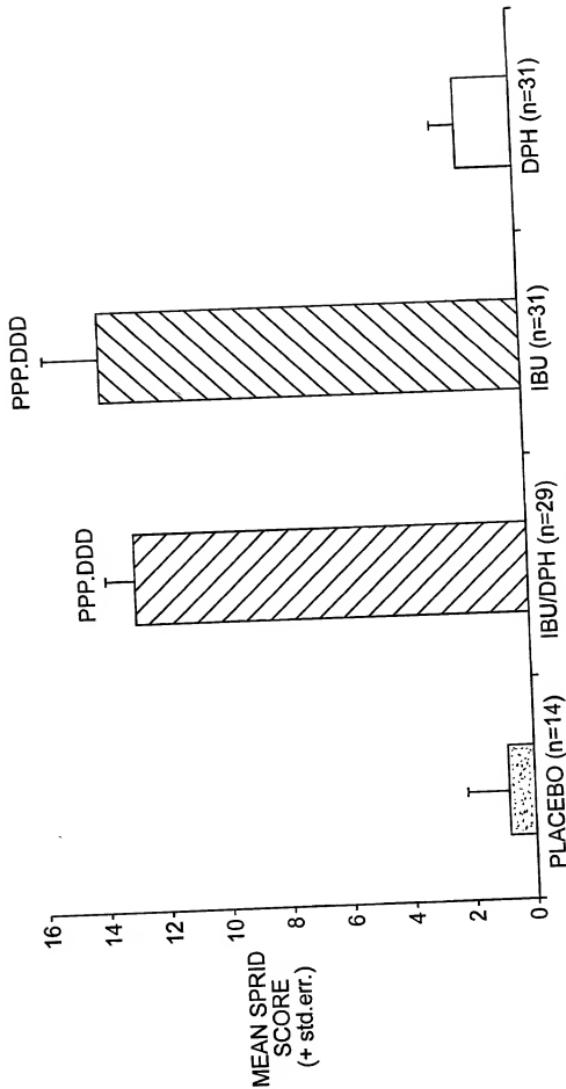
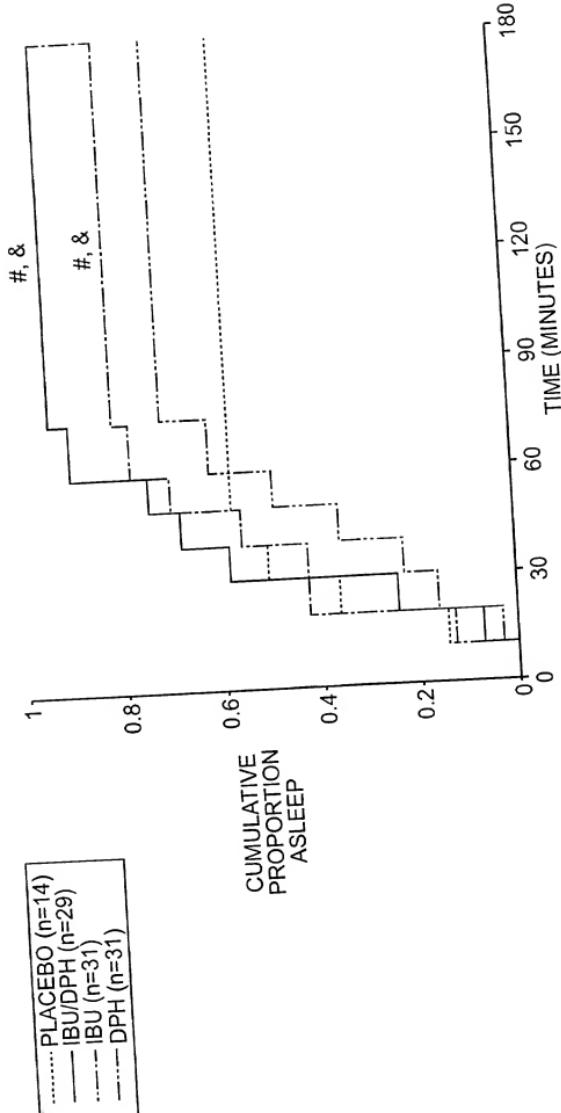


FIG. 3

CUMULATIVE PERCENT ASLEEP
STUDY A



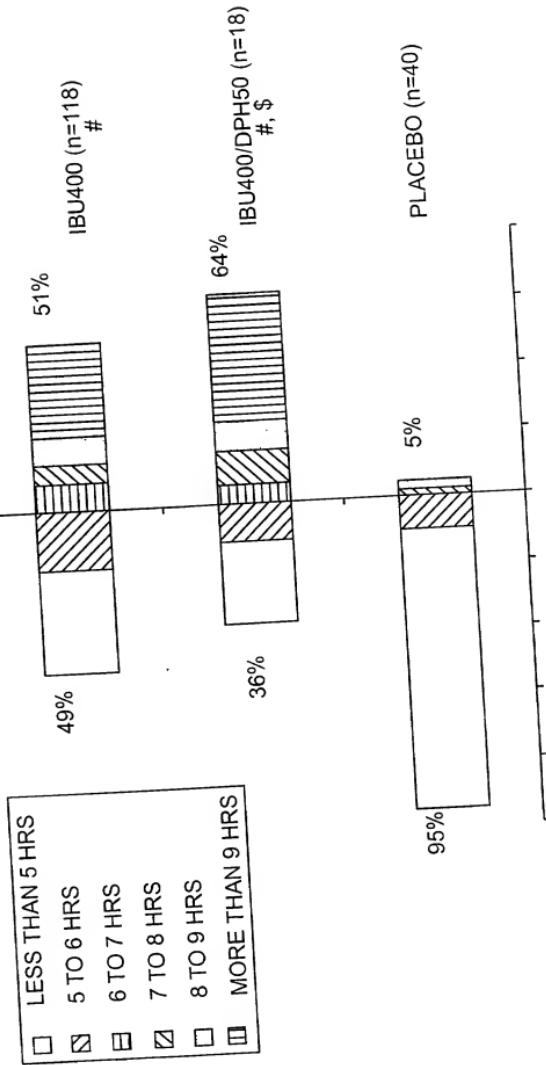
#: SIGNIFICANTLY BETTER THAN PLACEBO;

&: SIGNIFICANTLY BETTER THAN DPH.

NOTE: ALL TESTING WERE DONE AT 0.075 LEVEL OF SIGNIFICANCE

FIG. 4

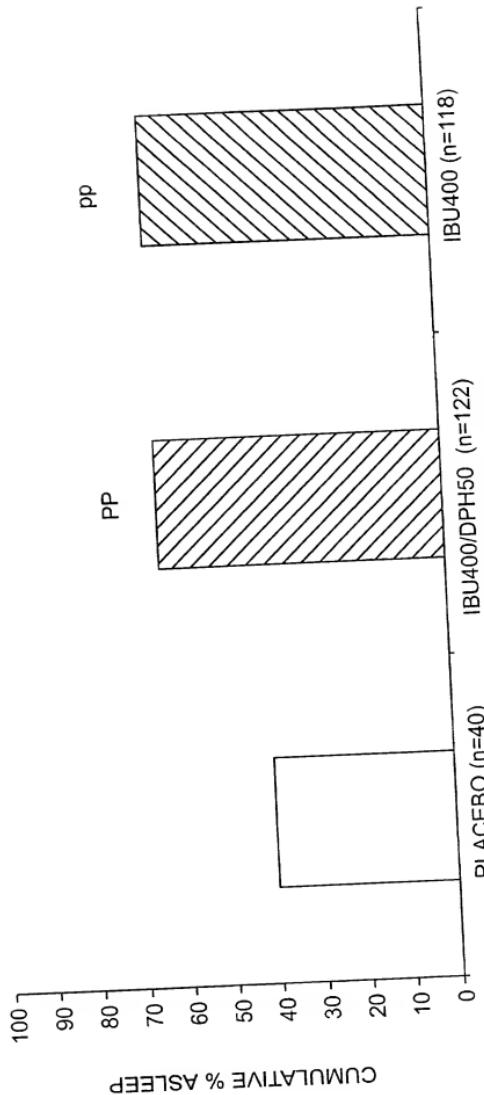
DURATION OF SLEEP
STUDY B



#: SIGNIFICANTLY BETTER THAN PLACEBO
\$: SIGNIFICANTLY BETTER THAN IBU 400 mg

FIG. 5

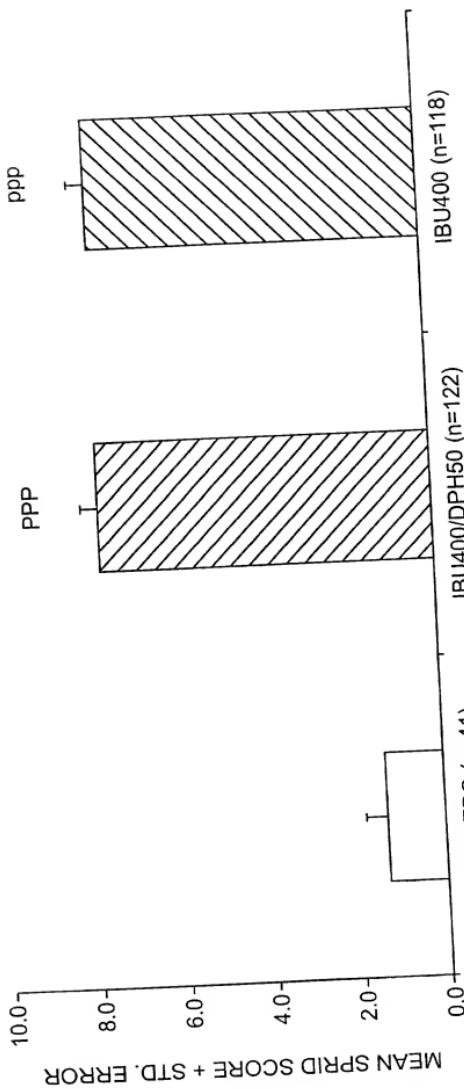
CUMULATIVE % OF SUBJECTS ASLEEP AT 60 MIN
STUDY B



PP
IBU400 (n=118)
IBU400/DPH50 (n=122)
PLACEBO (n=40)
PP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.01 LEVEL
pp: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.01 LEVEL
(BUT TECHNICALLY INELIGIBLE)

FIG. 6

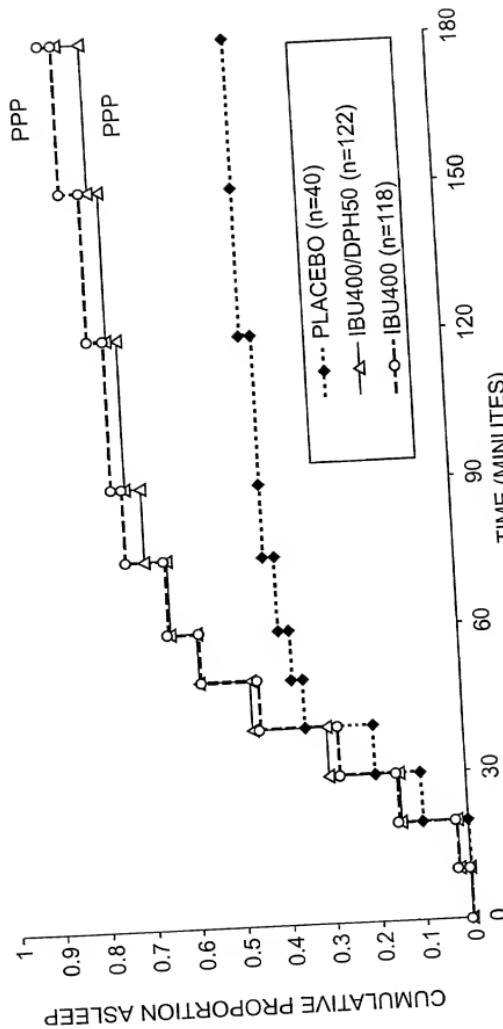
MEAN SPRID2 SCORES
STUDY B



PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL
ppp: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL
ppp: (BUT TECHNICALLY INELIGIBLE)

FIG. 7

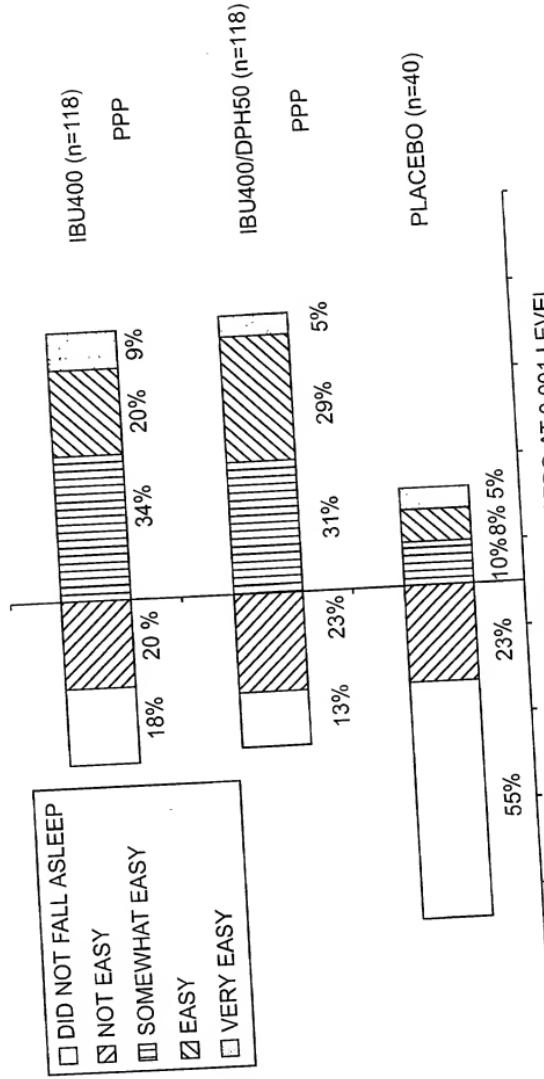
SLEEP LATENCY
STUDY B



PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL

FIG. 8

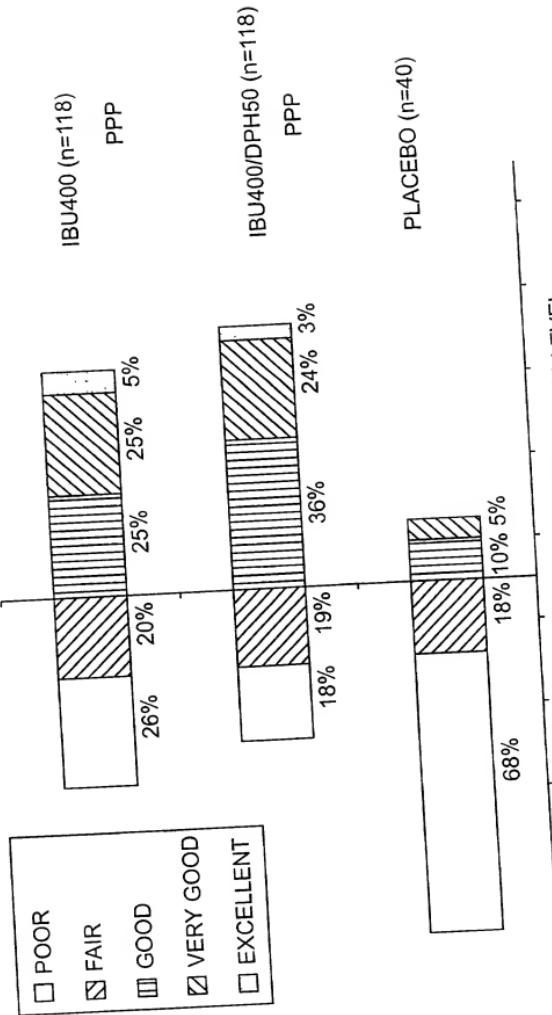
EASE OF FALLING ASLEEP
STUDY B



PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL
NOTE: OF THE 122 ITT SUBJECTS IN THE IBU400/DPH50 GROUP, 1 SUBJECT HAD MISSING DATA AND DATA FROM AN ADDITIONAL 3 SUBJECTS WERE CONSIDERED MISSING FOR THE PURPOSE OF ANALYSIS

FIG. 9

GLOBAL EVALUATION OF STUDY MEDICATION AS A SLEEP-AID
STUDY A



PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL
NOTE: OF THE 122 ITT SUBJECTS IN THE IBU400/DPH50 GROUP, 1 SUBJECT
HAD MISSING DATA AND DATA FROM AN ADDITIONAL 3 SUBJECTS WERE
MISSING FOR THE PURPOSE OF ANALYSIS

FIG. 10

MEAN PRID SCORES
STUDY B

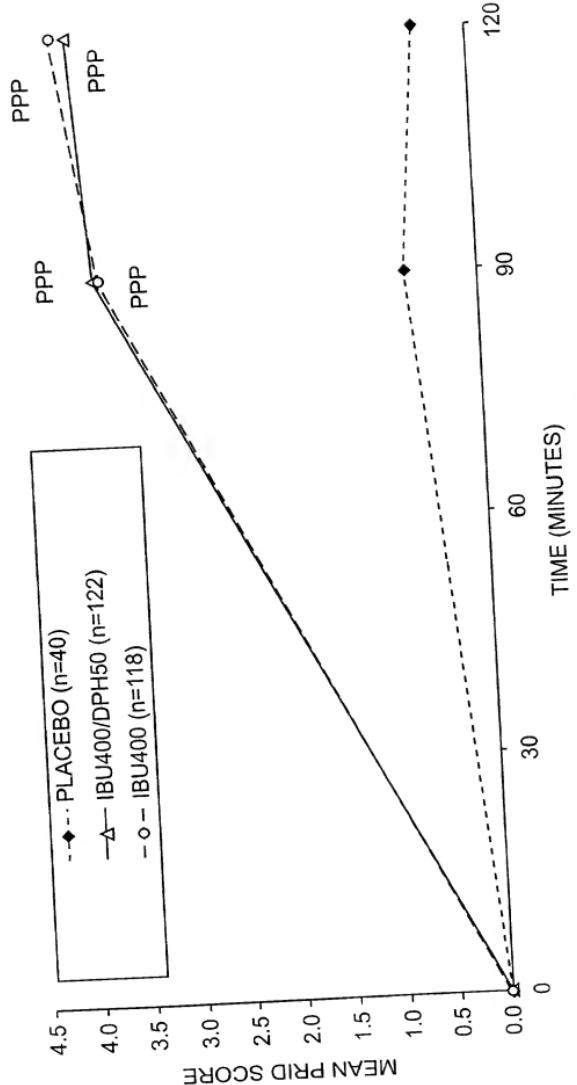
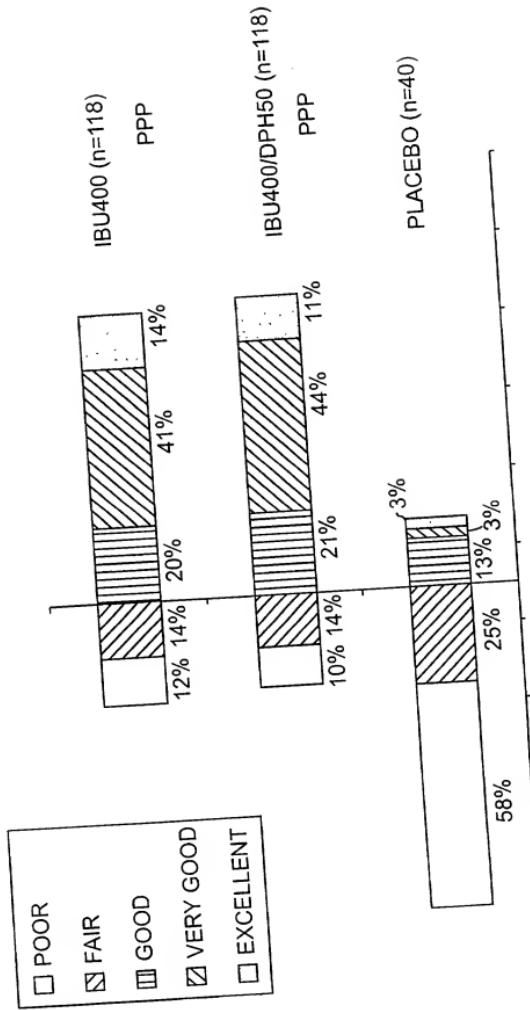


FIG. 11

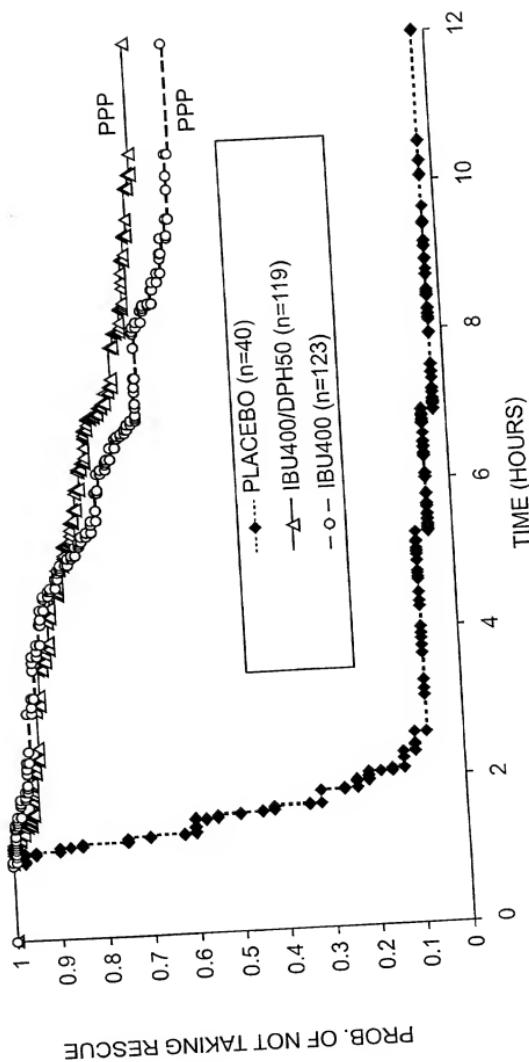
GLOBAL EVALUATION OF STUDY MEDICATION AS A PAIN RELIEVER
STUDY B



PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL
NOTE: OF THE 122 ITT SUBJECTS IN THE IBU400/DPH50 GROUP, 1 SUBJECT HAD MISSING DATA AND DATA FROM AN ADDITIONAL 3 SUBJECTS WERE CONSIDERED MISSING FOR THE PURPOSE OF ANALYSIS

FIG. 12

TIME TO RESCUE MEDICATION
STUDY C



PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL

FIG. 13

DURATION OF SLEEP
STUDY C

<input type="checkbox"/>	LESS THAN 5 HRS
<input checked="" type="checkbox"/>	5 TO 6 HRS
<input type="checkbox"/>	6 TO 7 HRS
<input type="checkbox"/>	7 TO 8 HRS
<input type="checkbox"/>	8 TO 9 HRS
<input checked="" type="checkbox"/>	MORE THAN 9 HRS

48%

IBU400 (n=123)

#

<input type="checkbox"/>	LESS THAN 5 HRS
<input checked="" type="checkbox"/>	5 TO 6 HRS
<input type="checkbox"/>	6 TO 7 HRS
<input checked="" type="checkbox"/>	7 TO 8 HRS
<input type="checkbox"/>	8 TO 9 HRS
<input checked="" type="checkbox"/>	MORE THAN 9 HRS

37%

IBU400/DPH50 (n=119)

#, \$

98%

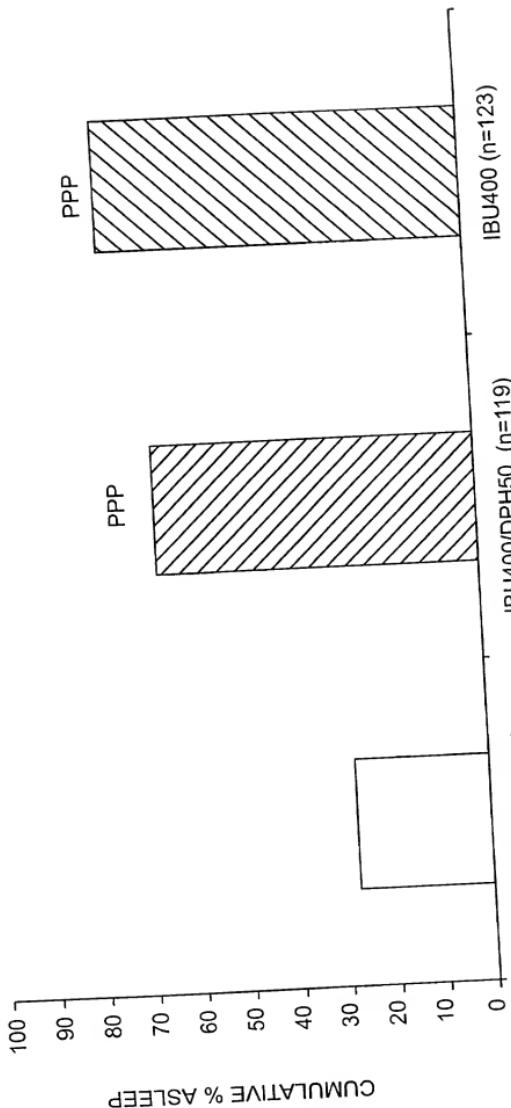
PLACEBO (n=40)

PLACEBO (n=119)

#: SIGNIFICANTLY BETTER THAN PLACEBO
\$: SIGNIFICANTLY BETTER THAN IBU 400 mg

FIG. 14

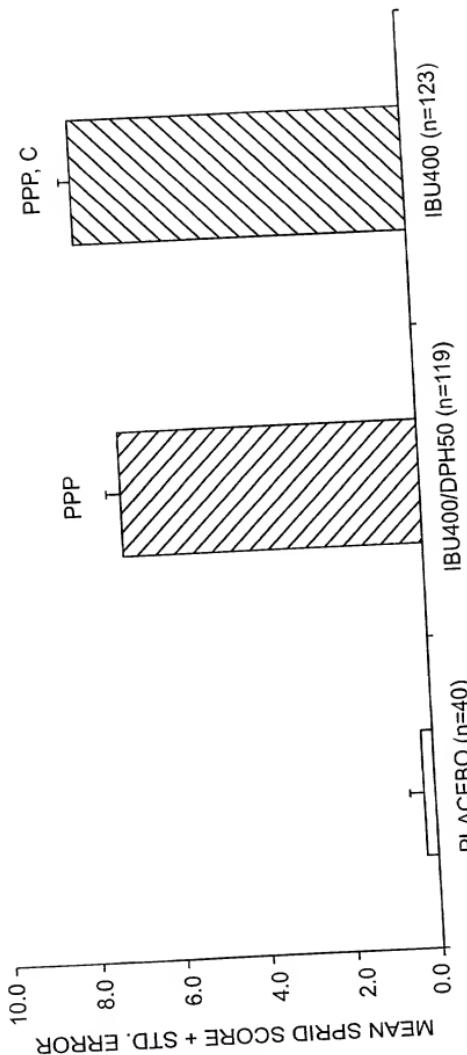
CUMULATIVE % OF SUBJECTS ASLEEP AT 60 MIN
STUDY C



PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL

FIG. 15

MEAN SPRID2 SCORES
STUDY C



PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL
C: SIGNIFICANTLY BETTER THAN IBUPROFEN 400 mg/DIPHENHYDRAMINE
HYDROCHLORIDE 50 mg COMBINATION AT 0.05 LEVEL

FIG. 16

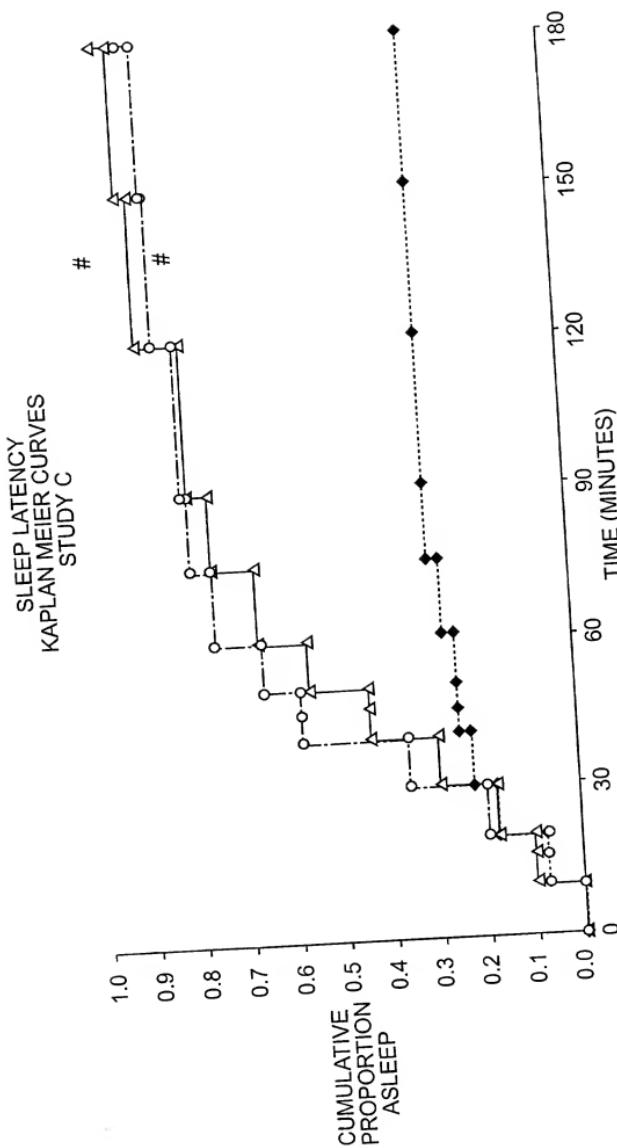
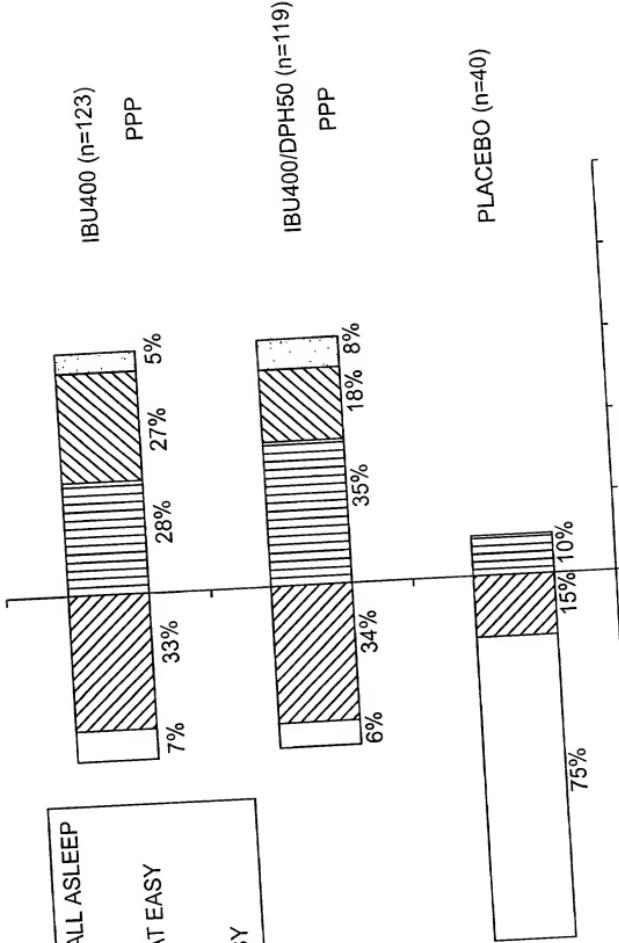


FIG. 17

SIGNIFICANTLY BETTER THAN PLACEBO

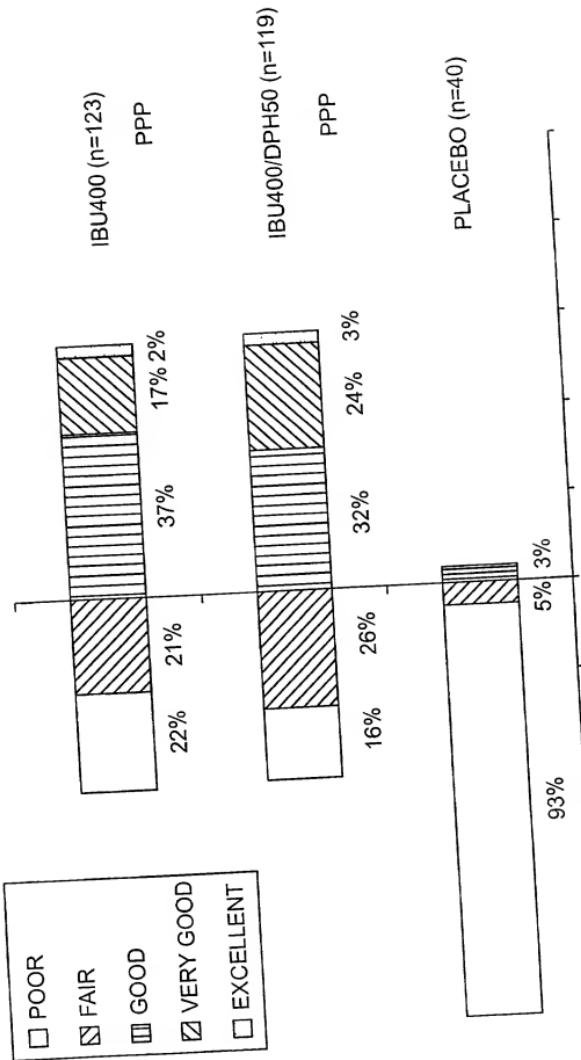
EASE OF FALLING ASLEEP STUDY C

- DID NOT FALL ASLEEP
- NOT EASY
- SOMEWHAT EASY
- EASY
- VERY EASY



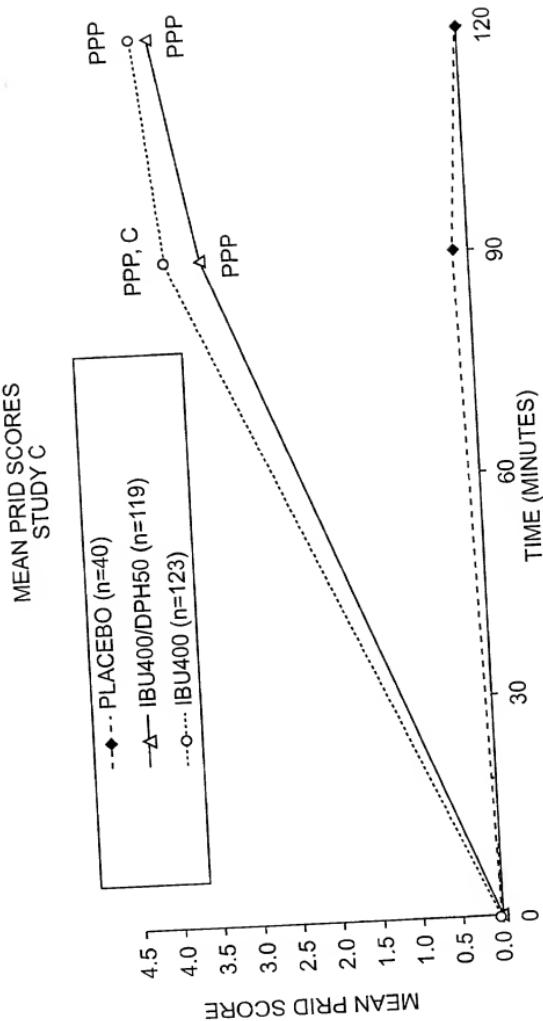
PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL
FIG. 18

GLOBAL EVALUATION OF STUDY MEDICATION AS A SLEEP-AID
STUDY C



PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL

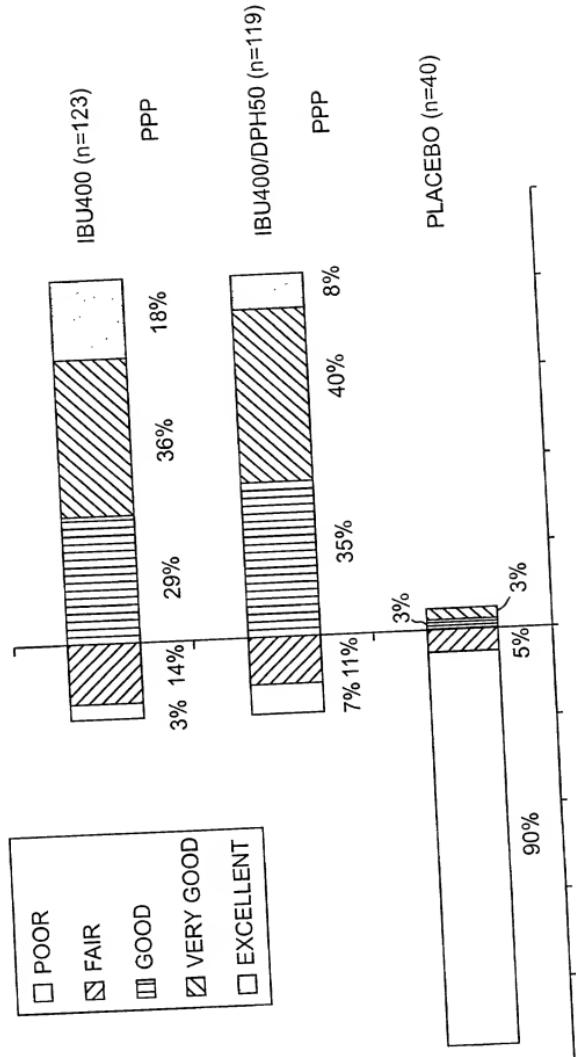
FIG. 19



PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL
 C: SIGNIFICANTLY BETTER THAN IBUPROFEN 400 mg/DIPHENHYDRAMINE
 HYDROCHLORIDE 50 mg COMBINATION AT 0.05 LEVEL

FIG. 20

GLOBAL EVALUATION OF STUDY MEDICATION AS A PAIN RELIEVER
STUDY C



PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL

FIG. 21

TIME TO RESCUE MEDICATION
KAPLAN MEIER CURVES
STUDY C

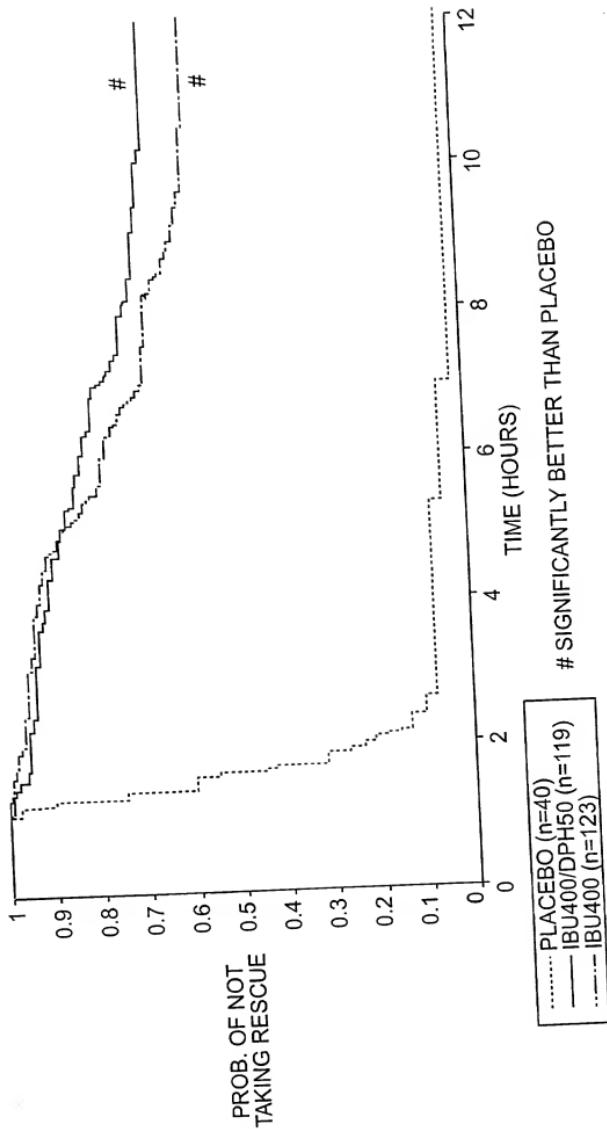
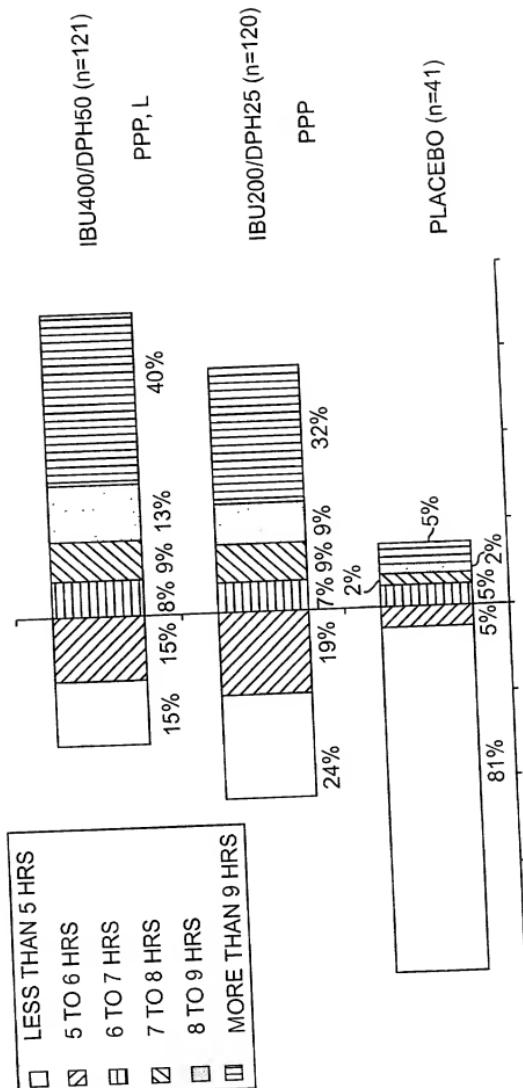


FIG. 22

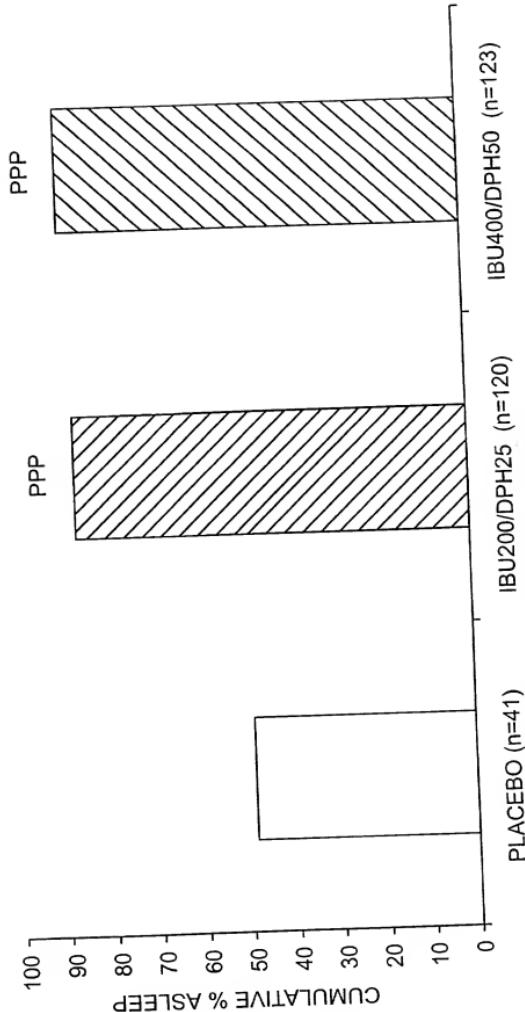
DURATION OF SLEEP
STUDY D



PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL
L: SIGNIFICANTLY BETTER THAN IBU200/DPH25 AT 0.05 LEVEL

FIG. 23

CUMULATIVE % OF SUBJECTS ASLEEP AT 60 MIN
STUDY D



PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL

FIG. 24

MEAN SPRID2 SCORES
STUDY D

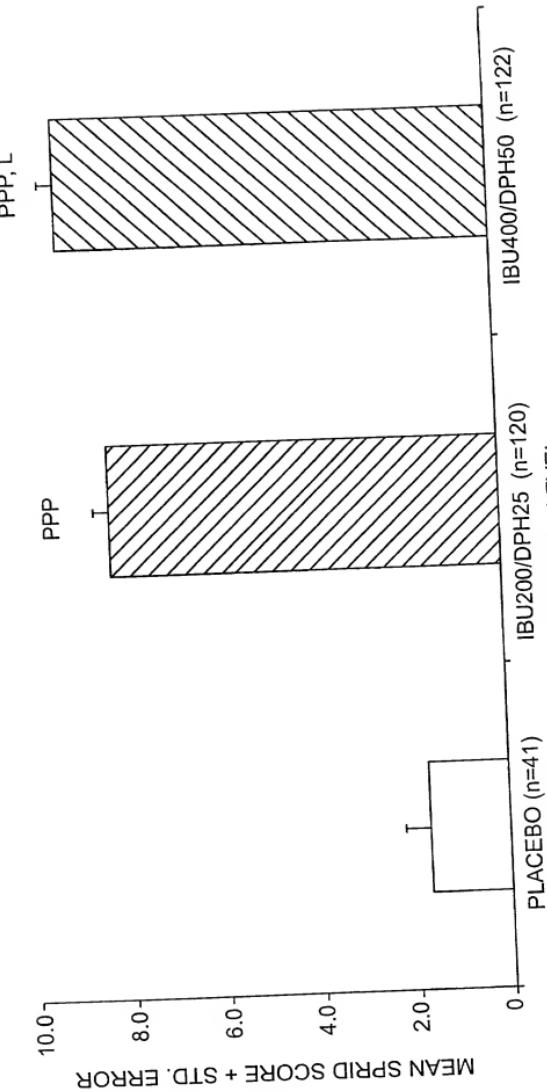


FIG. 25

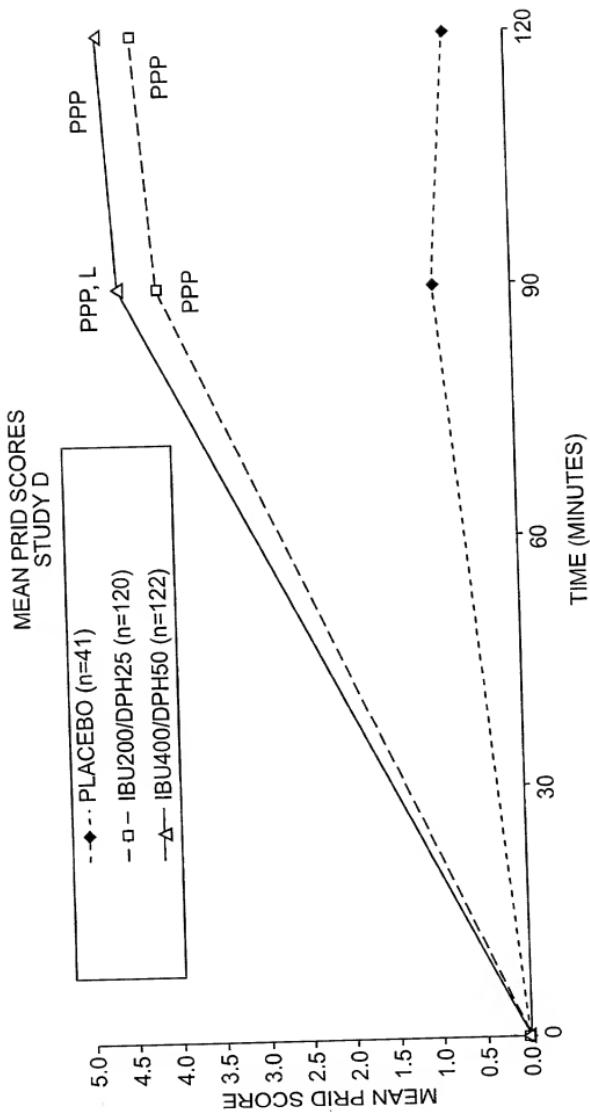


FIG. 26

GLOBAL EVALUATION OF STUDY MEDICATION AS A PAIN RELIEVER
STUDY D

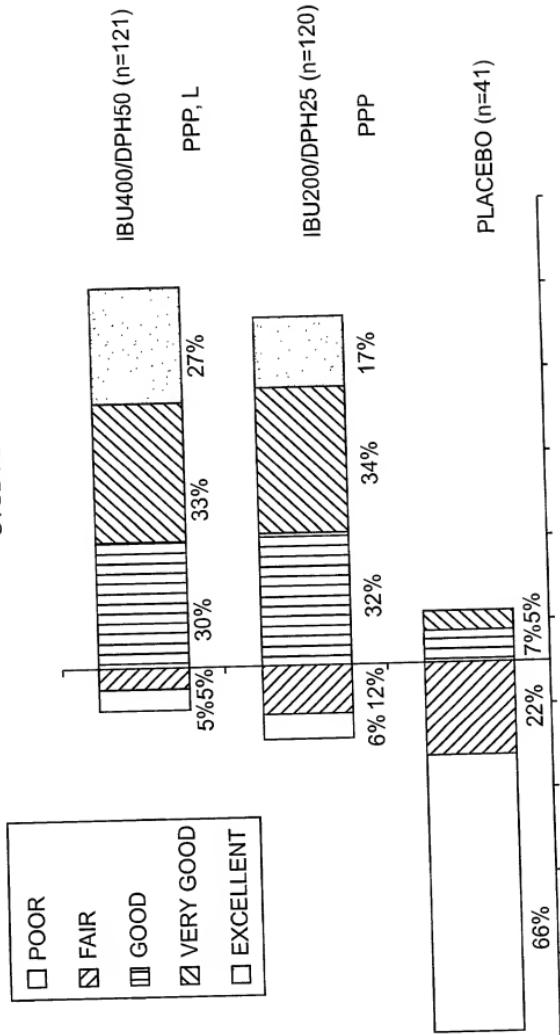
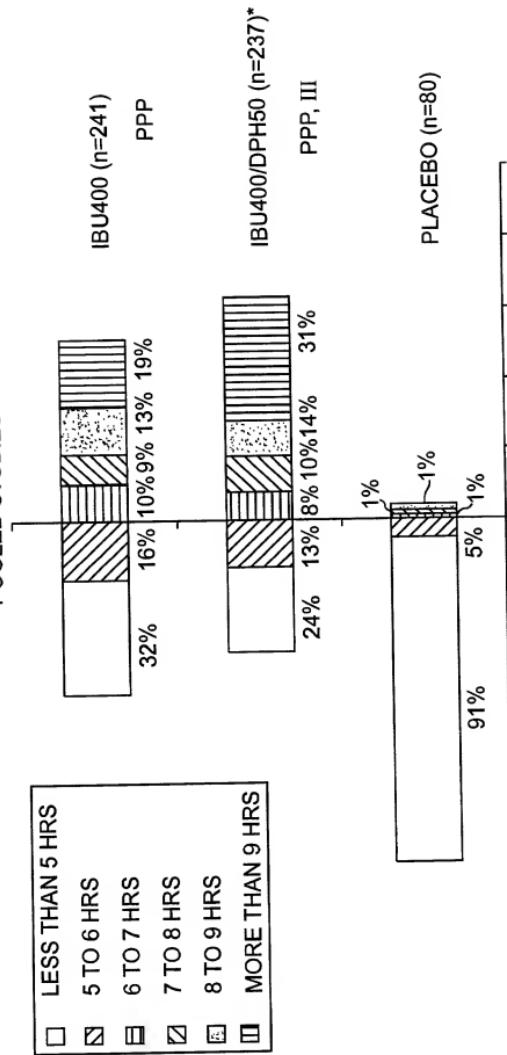


FIG. 27

DURATION OF SLEEP
POOLED STUDIES



PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL

III: SIGNIFICANTLY BETTER THAN IBU400mg AT 0.001 LEVEL
*OF THE 241 ITT SUBJECTS IN THE IBU400/DP50 GROUP, 1 SUBJECT HAD MISSING DATA AND DATA FROM

AN ADDITIONAL 3 SUBJECTS WERE CONSIDERED MISSING FOR THE PURPOSE OF ANALYSIS (THESE 4 SUBJECTS ARE FROM STUDY B)

FIG. 28

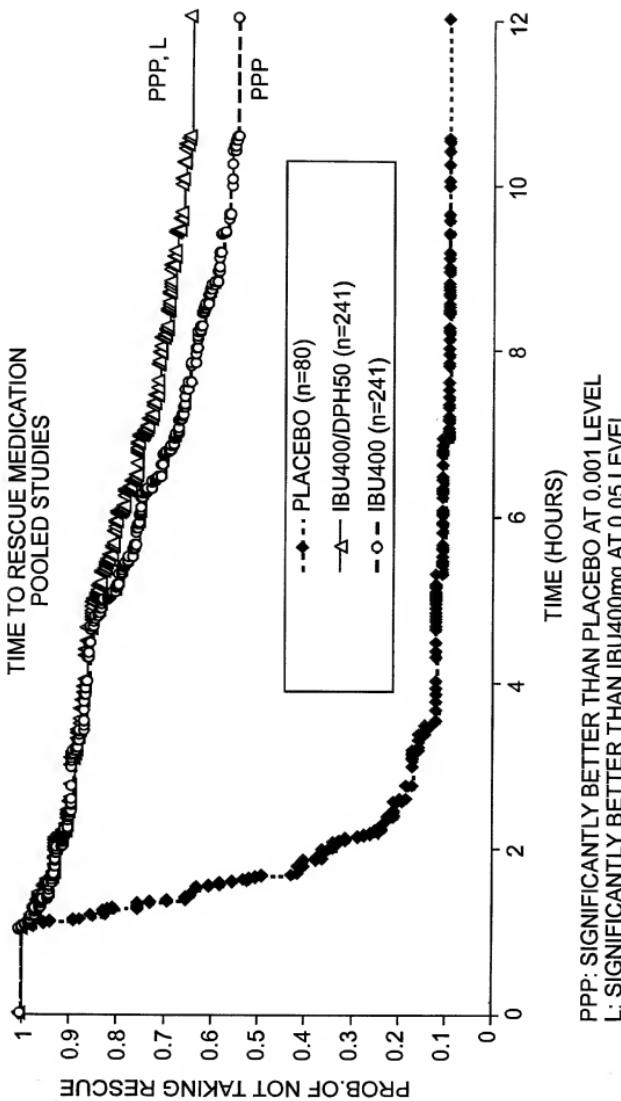


FIG. 29

PPP: SIGNIFICANTLY BETTER THAN PLACEBO AT 0.001 LEVEL
L: SIGNIFICANTLY BETTER THAN IBU400mg AT 0.05 LEVEL